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October 11, 1999

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99N-3089

The following are comments regarding the Draft Affirmative Agenda for International Activities, for FDA's Center for Food Safety and Applied Nutrition. The Association of Food and Drug Officials' Board of Directors appreciates the opportunity to provide comments prior to publication of the official agenda in the Federal Register.

The Association of Food and Drug Officials (AFDO) is the primary organization of federal, state, and local food and drug officials throughout the United States, including Canada. We are celebrating 103 years of activities which promote uniformity in the regulation of foods, drugs, and medical devices, through "cooperation and communication." These comments are directed toward the fostering of this primary goal of AFDO with respect to the regulation of imported foods.

AFDO agrees that the agenda as laid out by FDA in the Draft Affirmative Agenda will go far toward assuring that food products imported into the United States are in compliance with U.S. laws and regulations, and that adequate efforts will be made to ensure that universal standards developed by international bodies conform with those standards as long as FDA carries out the proposed agenda to the fullest.

AFDO's comments are therefore directed more toward activities between FDA/CFSAN and the States, which if implemented can significantly improve FDA oversight of imported foods. Under Roman numeral (I), Regulatory Activities, AFDO believes that CFSAN should improve and expand Partnership Agreements with the States to inspect and sample foods in "domestic import" status. In addition, several states cooperate with FDA to assist in the monitoring of border crossings, including international airports. Further, AFDO believes that the States can provide much assistance to FDA in conducting traceback investigations, up to the point of identifying the source of imported products which may be related to incidences of foodborne illness. FDA should actively pursue these partnerships to enhance its efforts to ensure that imported foods meet the same food safety requirements as domestically produced foods.

The same can be said for "Improving the Food Labeling Compliance" for imported foods. Several States have active programs for monitoring the labeling of all foods, but in particular imported foods which contain undeclared allergens, for instance. Again, FDA should pursue additional partnerships with the States in this area.

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AFDO believes that there may be some confusion regarding the terms "harmonization" and "equivalence," as referenced in the Draft Affirmative Agenda. Harmonization, in the context used by FDA, means "meeting the exact same requirements." On the other hand, "equivalency" should refer to the development of *systems* which produce equivalent results with respect to food safety. Therefore, AFDO recommends that "equivalency" stand apart from any headings which refer to "harmonization."

AFDO disagrees with the philosophy of continuing to issue "Certificates of for Export" (commonly referred to as "Certificates of Free Sale"), at least for products exported under the North American Free Trade Agreement (NAFTA). AFDO believes that such certificates should have been made obsolete under NAFTA and is currently working to discourage the continuation of this practice. AFDO considers these certificates to be an unnecessary barrier to free trade. Many states and localities also issue these certificates, sometimes with no regulatory foundation to do so. AFDO is willing to work closely with FDA on this issue.

With respect to "International Harmonization" and CFSAN participation in Codex, AFDO brings FDA's attention to the fact that we are also members of the U.S. Delegation to the Codex Hygiene Committee and have provided some expert input into the standards committee, and are participating in the Codex ad hoc Juice Task Force. We therefore believe that AFDO has the ability to offer assistance to FDA in this area and would entertain any requests from FDA for collaboration on various issues before the Commission, in order to provide State and local input into the international issues addressed by Codex which impact State programs.

Further, AFDO has been a leader in the areas of integration and uniformity, which helps to position both federal and state programs for international acceptance, a very important issue to us all these days. AFDO can be of great assistance to FDA on this issue in the not too distant future, when the European Union and others begin demanding equivalence in the regulation of foods throughout the U.S.

In conclusion, AFDO looks forward to a closer and more productive relationship with FDA in the regulation of imported foods. Again, we wish to thank FDA for the privilege of commenting on this proposal.

Respectfully submitted,

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President

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